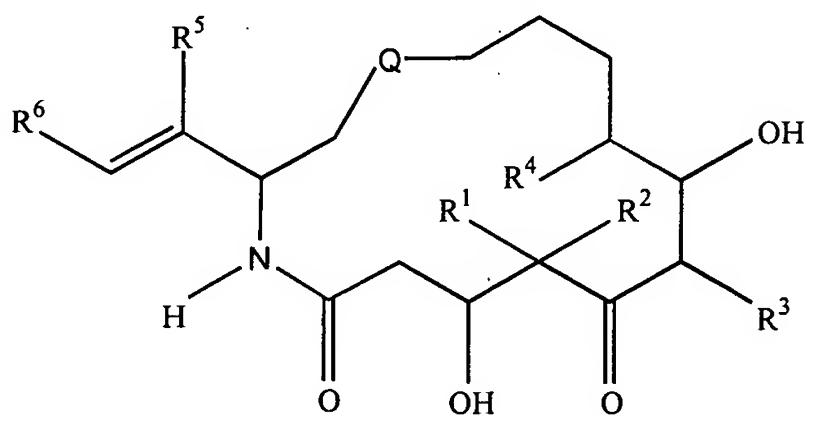
IN THE CLAIMS:

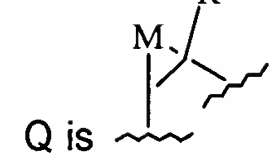
The following is a complete listing of all claims upon entry of this Amendment:

1 (Currently amended). A process for formulating, for parenteral administration, an epothilone analog represented by formula I:



I

wherein:



Q is ;

M is oxygen;

each R^1, R^2, R^3, R^4, R^5, and R^7 is, independently, selected from the group consisting of hydrogen, alkyl, substituted alkyl, aryl, substituted aryl and heterocyclo, and wherein R^1 and R^2 are alkyl, they can be joined to form cycloalkyl;

R^6 is selected from the group consisting of hydrogen, alkyl, substituted alkyl, aryl, substituted aryl, cycloalkyl, and heterocyclo ~~and substituted heterocyclo~~;

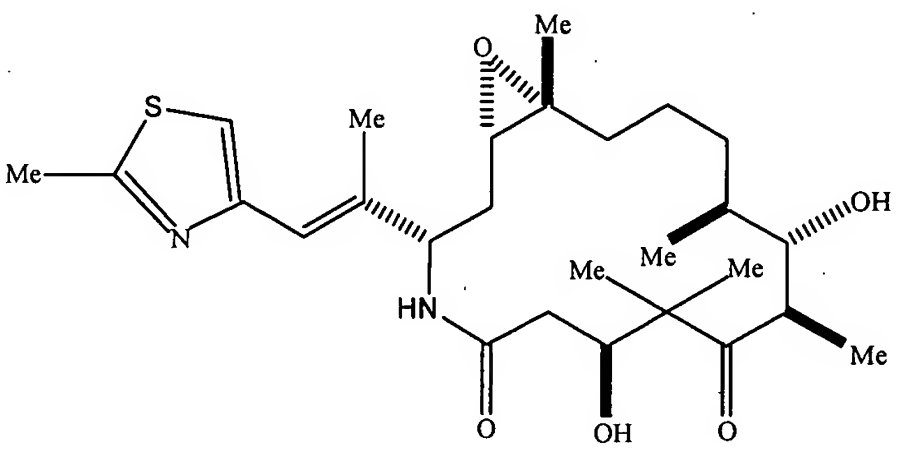
and any salts, solvates, or hydrates thereof, comprising the following steps:

a) dissolving said epothilone analog in a mixture of at least about 50% by volume tertiary-butanol in water to form a solution;

b) performing primary drying of said solution at a temperature of from about -10°C to about -40°C under vacuum of from about 50 millitorr to about 300 millitorr for from about 24 hours to about 96 hours to form a primary lyophilized product; and

c) performing secondary drying of the primary lyophilized product at a temperature of from about 10 °C to about 30°C under vacuum of from about 50 millitorr to about 300 millitorr for from about 24 hours to about 96 hours to provide a lyophilized product of the epothilone analog.

2 (Previously presented). The process of claim 1 wherein said epothilone analog is represented by formula II:



II

3 (Previously presented). The process of claim 1 wherein step a) comprises first, wetting said epothilone analog with a mixture of at least about 60% tertiary-butanol in water, and then adding sufficient water, or a mixture of tertiary-butanol and water, so that the resulting solution contains from about 2 mg/mL to about 30 mg/mL of said epothilone analog in a mixture of from about 50% to about 80% by volume tertiary-butanol in water.

4 (Previously presented). The process of claim 2 wherein step a) comprises first, wetting said epothilone analog with a mixture of at least about 60% tertiary-butanol in water, and then adding sufficient water, or a mixture of tertiary-butanol and water, so that the resulting solution contains from about 2 mg/mL to about 30 mg/mL of said epothilone analog in a mixture of from about 50% to about 80% by volume tertiary-butanol in water.

5 (Previously presented). The process of claim 3 wherein in step a) said epothilone analog is initially wetted with a mixture of from about 60% to about 95% by volume tertiary-butanol in water.

6 (Previously presented). The process of claim 4 wherein in step a) said epothilone analog is initially wetted with a mixture of from about 60% to about 95% by volume tertiary-butanol in water.

7 (Canceled).

8 (Previously presented). The process of claim 2 wherein said primary drying in step b) is carried out at a temperature of from about -25°C to -40°C and a pressure of from about 200 to 300 millitorr.

9 (Canceled).

10 (Previously presented). The process of claim 2 wherein said secondary drying in step c) is carried out at a temperature of from about 25°C to 30°C and a pressure of from about 150 to 300 millitorr.

11 (Previously presented). The process of claim 30 wherein said surfactant is polyethoxylated castor oil.

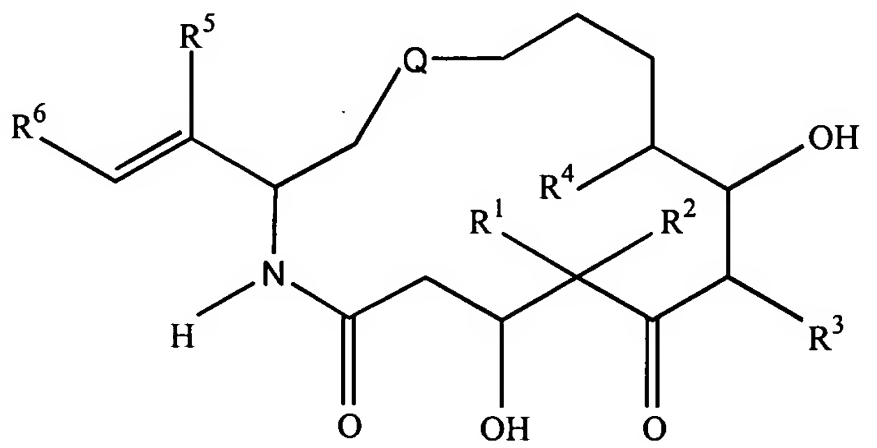
12 (Previously presented). The process of claim 32 wherein said surfactant is polyethoxylated castor oil.

13 (Previously presented). The process of claim 30 wherein said second vial contains an amount of said mixture sufficient to form a solution of from about 2 mg/mL to about 4 mg/mL of said epothilone analog therein.

14 (Canceled).

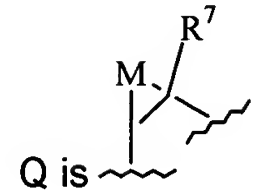
15 (Currently amended). A pharmaceutical preparation comprising~~, in a first vial~~ a lyophilized epothilone analog in a first vial prepared by dissolving an epothilone analog in a

t-butanol and water solution, drying the solution under vacuum, and performing a secondary drying to obtain the lyophilized epothilone analog, ~~and in a second vial, a quantity of a suitable solvent or solvent mixture therefor such that when the contents of said first and second vials are combined, the lyophilized epothilone analog is reconstituted into a resulting solution, said epothilone analog being~~ wherein the epothilone analog is represented by formula I:



I

wherein:

Q is 

;

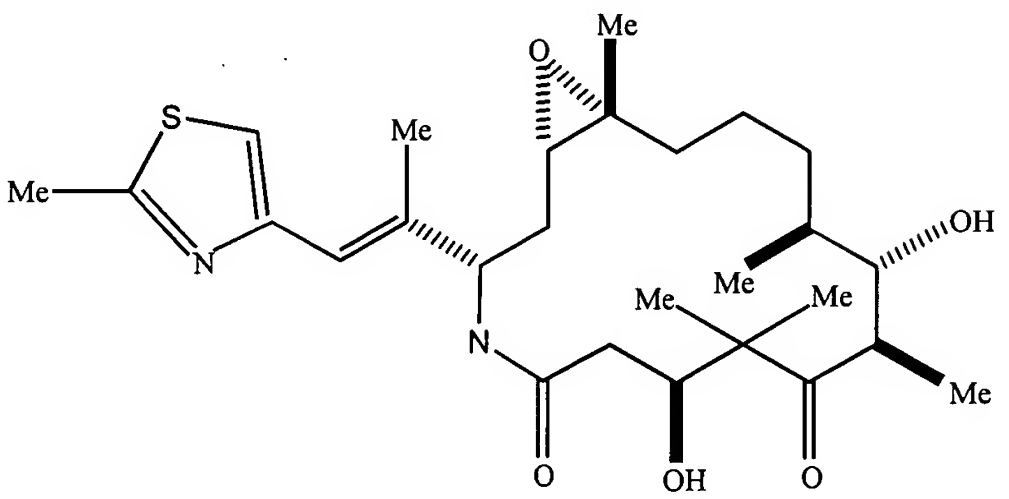
M is oxygen;

each R^1, R^2, R^3, R^4, R^5, and R^7 is, independently, selected from the group consisting of hydrogen, alkyl, substituted alkyl, aryl, substituted aryl and heterocyclo, and wherein R^1 and R^2 are alkyl, they can be joined to form cycloalkyl;

R^6 is selected from the group consisting of hydrogen, alkyl, substituted alkyl, aryl, substituted aryl, cycloalkyl, and heterocyclo ~~and substituted heterocyclo~~;

and any salts, solvates, or hydrates thereof.

16 (Original). The pharmaceutical preparation of claim 15 wherein said epothilone analog is represented by formula II:



II

17 (Currently Amended). The pharmaceutical preparation of claim 19 ~~16~~ wherein said solvent or solvent mixture comprises a nonionic surfactant that is polyethoxylated castor oil.

18 (Canceled).

19 (Currently amended). The pharmaceutical preparation of claim 15, further comprising a second vial containing a quantity of a suitable solvent or solvent mixture therefor such that the contents of said first and second vials can be combined to reconstitute the lyophilized epothilone analog into a resulting solution, ~~A process for forming a pharmaceutical composition for parenteral administration comprising mixing the contents of the first and second vials of the pharmaceutical preparation of claim 16 to effect solution of said lyophilized epothilone analog and diluting the resultant solution~~ and further comprising a third vial with a quantity of a suitable parenteral diluent for diluting the resulting solution such that the concentration of said epothilone analog therein is from about 0.1 mg/mL to about 0.9 mg/mL.

20-21 (Canceled).

22 (Currently amended). The ~~process~~ pharmaceutical preparation of claim 19 wherein said diluent is Lactated Ringer's Injection.

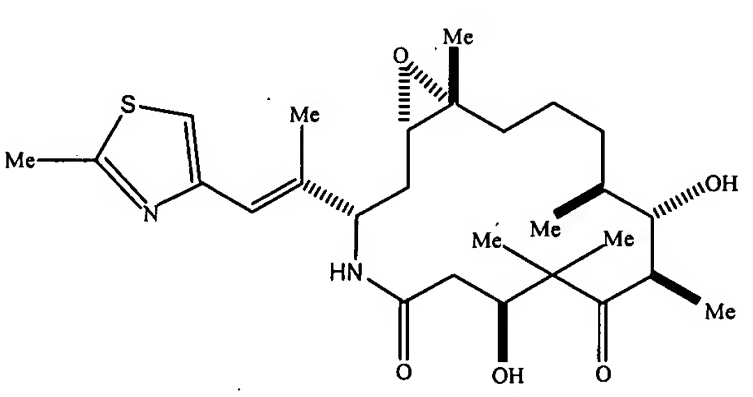
23-29 (Canceled).

30 (Previously presented). The process of claim 1, further comprising the step of:

d) packaging said lyophilized product of the epothilone analog in a first vial and packaging in a second vial a sufficient quantity of a mixture comprising at least one suitable nonionic surfactant and at least one dehydrated alcohol to effect reconstitution of the lyophilized product.

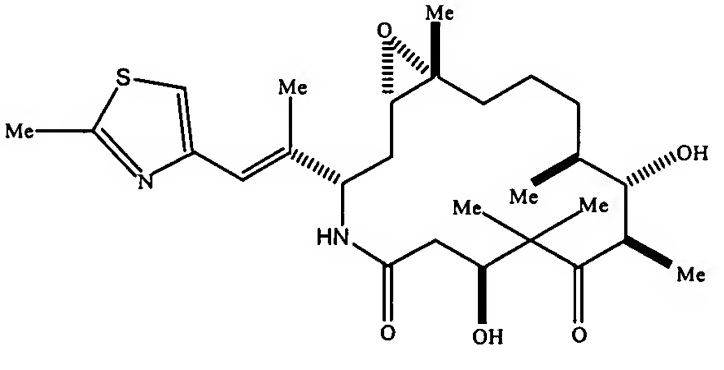
31 (Previously presented). The process of claim 30 wherein the mixture comprises about equal parts by volume of anhydrous ethanol and the at least one nonionic surfactant.

32 (Previously presented). The process of claim 30 wherein said epothilone analog is:



33 (Canceled).

34 (Previously presented). A process for formulating, for parenteral administration, an epothilone analog having the formula:



comprising:

a) dissolving said epothilone analog in a mixture of tertiary butanol and water to form a solution, wherein the mixture comprises at least about 50% by volume tertiary butanol;

b) performing primary drying of said solution at a temperature, chamber pressure and period of time sufficient to form a primary lyophilized product; and

c) performing secondary drying of the primary lyophilized product at a temperature, chamber pressure and for a period of time sufficient to form a lyophilized product of the epothilone analog.

35 (Previously presented) The process of claim 34, wherein said step a) of dissolving said epothilone analog is carried out at a temperature below ambient temperature.

~~35~~ 55 (Currently Amended) The process of claim 34, wherein said step a) of dissolving said epothilone analog is carried out at a temperature in the range of from about 5°C to about 15°C.

36 (Previously presented). The process of claim 34, wherein said step a) of dissolving said epothilone analog comprises first, wetting said epothilone analog with a mixture of at least about 60% by volume tertiary-butanol in water, and then adding sufficient water, or a mixture of tertiary-butanol and water, so that the resulting solution contains at least about 50% by volume tertiary-butanol in water.

37 (Previously presented). The process of claim 34, wherein said step a) of dissolving said epothilone is carried out in the absence of an excipient.

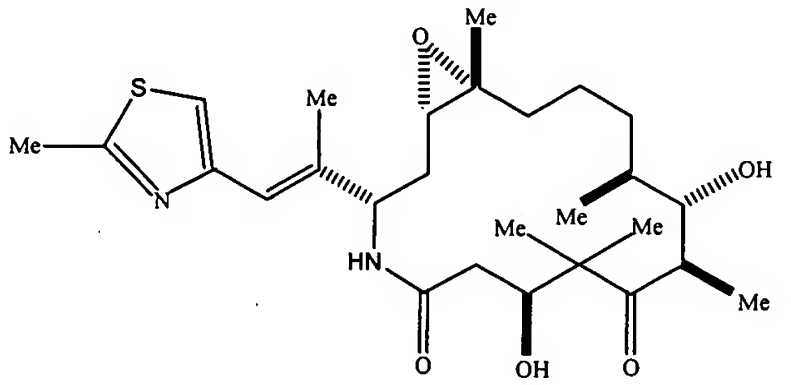
38 (Previously presented). The process of claim 34 wherein said primary drying in step b) is carried out at a temperature of from about -10°C to -40°C and at a chamber pressure of from about 50 to 300 millitorr for a period of up to about 96 hours.

39 (Previously presented). The process of claim 38 wherein said secondary drying in step c) is carried out at a temperature of from about 10°C to 30°C and at a chamber pressure of from about 150 to 300 millitorr for a period of up to about 96 hours.

40 (Previously presented). The process of claim 34, further comprising the step of:

d) packaging said lyophilized product of the epothilone analog in a first vial and packaging in a second vial a sufficient quantity of a solvent mixture to effect reconstitution of the epothilone analog, wherein the solvent mixture of the second vial comprises at least one suitable nonionic surfactant and at least one anhydrous alcohol.

41 (Previously presented). A process for formulating, for parenteral administration, an epothilone analog represented by formula II:



comprising:

a) dissolving said epothilone analog to form a solution, comprising first, wetting said epothilone analog with a mixture of at least about 60% by volume tertiary-butanol in water, and then adding sufficient water, or a mixture of tertiary-butanol and water, so that the resulting solution contains at least about 50% by volume tertiary-butanol in water, wherein said step of dissolving is carried out at a temperature below ambient temperature;

b) performing primary drying of said solution at a temperature, chamber pressure and for a period of time sufficient to form a primary lyophilized product; and

c) performing secondary drying of the primary lyophilized product at temperature, chamber pressure and for a period of time sufficient to form a lyophilized product of the epothilone analog.

42 (Currently amended). The process of claim 41 wherein,

step b) of primary drying of said solution is performed at a temperature of about -10°C to about -40°C under vacuum of from about 50 millitorr to about 300 millitorr for from about 24 hours to about 96 hours; and

step c) of secondary drying is performed at a temperature of from about 10°C to about 30°C under vacuum of from about 50 millitorr to about 300 millitorr for from about 24 hours to about 96 hours to provide a lyophilized product of the epothilone analog.

43 (Previously presented). The process of claim 42 wherein,

step a) of dissolving said epothilone analog is carried out at a temperature of from about -5°C to about 15°C.

44 (Previously presented). The process of claim 43 wherein,

step a) of dissolving said epothilone analog is carried out in the absence of an excipient.

45 (Previously presented). The process of claim 43, further comprising the step of:

d) packaging said lyophilized product of the epothilone analog in a first vial and packaging in a second vial a sufficient quantity of a solution to effect reconstitution of the lyophilized epothilone analog, wherein the solution of the second vial comprises about equal amounts of at least one suitable nonionic surfactant and at least one anhydrous alcohol.

46 (Previously presented) A pharmaceutical preparation comprising a lyophilized epothilone analog prepared according to claim 1.

47 (Previously presented) A pharmaceutical preparation comprising a lyophilized epothilone analog prepared according to claim 2.

48 (Previously presented) A pharmaceutical preparation comprising a lyophilized epothilone analog prepared according to claim 34.

49 (Previously presented) A pharmaceutical preparation comprising a lyophilized epothilone analog prepared according to claim 39.

50 (Previously presented) A pharmaceutical preparation comprising a lyophilized epothilone analog prepared according to claim 43.

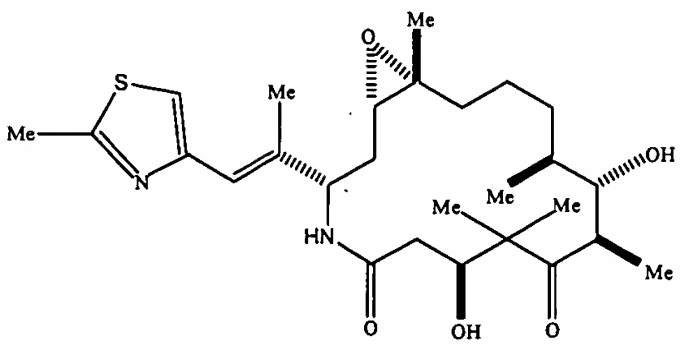
51 (Previously presented) A pharmaceutical product comprising at least a first and a second vial wherein the first vial contains a lyophilized epothilone analog prepared according to claim 2, and the second vial contains a sufficient quantity of a solution to effect reconstitution of the lyophilized epothilone analog, wherein the solution of the second vial comprises about equal amounts of at least one suitable nonionic surfactant and at least one anhydrous alcohol.

52 (Previously presented) A method of treating a patient comprising, mixing the contents of the first and second vials of the pharmaceutical product of claim 51 to provide an epothilone solution, diluting the epothilone solution with a quantitiy of a suitable parenteral diluent to prepare an intravenous formulation, and administering the intravenous formulation to the patient.

53 (Previously presented) A pharmaceutical product comprising at least a first and a second vial wherein the first vial contains a lyophilized epothilone analog prepared according to claim 34, and the second vial contains a sufficient quantity of a solution to effect reconstitution of the lyophilized epothilone analog, wherein the solution of the second vial comprises about equal amounts of at least one suitable nonionic surfactant and at least one anhydrous alcohol.

54 (Previously presented) A method of treating a patient comprising, mixing the contents of the first and second vials of the pharmaceutical product of claim 53 to provide an epothilone solution, diluting the epothilone solution with a quantitiy of a suitable parenteral diluent to prepare an intravenous formulation, and administering the intravenous formulation to the patient.

56 (New). A process for preparing a lyophilized epothilone analog wherein the epothilone analog has the formula,



comprising the steps of dissolving the epothilone analog in a t-butanol and water solution, drying the solution under vacuum and performing a secondary drying to obtain the lyophilized epothilone analog.

57 (New). A pharmaceutical product comprising a lyophilized epothilone analog prepared according to claim 56.

58 (New) A method of treating a patient comprising reconstituting the lyophilized epothilone analog prepared according to claim 56 to obtain an epothilone analog solution, diluting the epothilone analog solution in a suitable parenteral diluent to prepare an intravenous formulation, and administering the intravenous formulation to the patient.